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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,829	09/09/2003	Nikolai M. Krivitski	86017.000037	1750

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EXAMINER	
PANI, JOHN	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
06/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/657,829	KRIVITSKI ET AL.	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,16-22 and 28-31* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,16-20 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/16/2011 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,089,103 to Smith ("Smith '103").

4. Smith '103 discloses:

In reference to Claim 29

A method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) having a longitudinal axis (see Fig. 3) to pass a portion of the guide

wire through a terminal port ("distal opening") of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); sensing (see col. 4 lines 42-60) with a sensor (4) the indicator at a location located along the longitudinal axis intermediate the terminal port and the injection port (note that at least a portion of the sensor is located intermediate the terminal and injection ports in a radial direction with respect to the longitudinal axis); and calculating the blood flow rate (col. 4 lines 20 – col. 5 line 20) based on passage of the indicator through the terminal port (col. 4 lines 45-53; the pressure sensing of combined sensor 4 sets a timer used in the calculation) and the sensed indicator (col. 4 lines 55-60; i.e. via the temperature measuring of combined sensor 4).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 14, 17, 19, 20, 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,089,103 to Smith ("Smith '103") US in view of Pat. No. 6,343,514 to Smith ("Smith '514").

In reference to Claim 14

Smith ‘103 discloses a method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) having a longitudinal axis (see Fig. 3) to pass a portion of the guide wire through a terminal port (“distal opening”) of the indicator lumen; passing an indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) located along the longitudinal axis (see Fig. 3; 16 is located along the longitudinal sense in the same sense that port 34 is in Fig. 17 of the instant application) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); calculating the blood flow rate (see col. 5 line 60 – col. 6 line 1). Smith ‘103 further discloses that a volume less than a total volume of the indicator passed through the indicator lumen is injected into the blood vessel (see col. 4 lines 19-34). However, it is unclear whether Smith '103 calculates the blood flow rate as a function of less than a total volume the indicator passed through the terminal port. Smith ‘103 does however note that the flow parameter is calculated similarly to the method found in WO 97/27802, of which Smith '514 is a continuation (col. 5 lines 60-65).

Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have similarly used the total volume of injected indicator to determine the blood flow rate, as Smith ‘103 explicitly states that this method “is suitable for the determination of the so called Coronary Fractional

Reserve (CRF)" (col. 5 lines 60-63), and Smith '103 uses the blood flow rate to calculate CFR.

Because Smith '514 discloses using the total volume of injected indicator to calculate the blood flow rate, and Smith '103 discloses that the total volume of injected indicator is less than the total volume of the indicator passed through the indicator lumen, this combination renders obvious the claimed invention.

In reference to Claim 17

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses passing the indicator through the indicator lumen to contact a portion of the guide wire (col. 4 lines 34-37).

In reference to Claim 19

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses calculating the blood flow rate comprises compensating for a volume of the indicator passing through the terminal port (for example by acknowledging that indicator passes through both the terminal port and injection ports 16 and using this total volume).

In reference to Claim 20

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses the calculated blood flow rate is described by a relationship $Q = (k(T_b-T_i)*V(1-a))/S$, where Q is the calculated blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator, T_b is a temperature of a measured flow prior to injection of the indicator, T_i is a temperature of

the indicator prior to entering the measured flow, V is a volume of the indicator, S is an area under a temperature versus time curve resulting from a mixing of the indicator and a is a portion of the indicator passing through the terminal port, the calculated blood flow rate being a value provided by an appropriate selection of k, T_b, T_i, V, S, and a. (Note: This limitation has been interpreted to essentially require that for the calculated flow value, the flow value calculated in claim 14 could be obtained by choosing appropriate values for the variables in the cited relationship. The "blood flow rate" calculated in claim 14 is essentially some numerical value, and any numerical value could be generated using the claimed relationship of claim 20 by selecting the appropriate combination of values for the parameters).

In reference to Claim 28

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses comprising sensing the indicator along the longitudinal axis intermediate the terminal port and the injection port along a direction of blood flow (see Fig. 3, the sensor 4 is located intermediate the terminal port and the injection port at least in a direction orthogonal to the longitudinal axis of the catheter 14; this sensing occurs along the longitudinal axis as shown in Fig. 3).

In reference to Claim 31

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above), and Smith '514 discloses wherein calculating the blood flow rate includes quantifying a first amount of the indicator passing through the terminal port (note that Smith '514 quantifies the total volume of injected liquid by using it as a variable "V"; in Smith '103,

"V" would include the amount of indicator passing through the terminal port and thus would be "a first amount of the indicator passing through the terminal port"; in other words, "a first amount of the indicator" is interpreted as reading on the total amount of indicator exiting the catheter, and this amount, at least in part, passes through the terminal port; additionally or alternatively, in Smith '103, "V" would include the amount of indicator passing through the terminal port, and this amount would have a determined value –i.e. be quantified- because it is part of a larger quantified value).

In reference to Claim 30

Smith '103 discloses a method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) having a longitudinal axis (see Fig. 3) to pass a portion of the guide wire through a terminal port ("distal opening") of the indicator lumen; passing an indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) located along the longitudinal axis (see Fig. 3; 16 is located along the longitudinal sense in the same sense that port 34 is in Fig. 17 of the instant application) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); sensing (see col. 4 lines 42-60) with a sensor (4) passage of the indicator in the blood flow along a length of the catheter (by at least sensing the temperature gradient caused by indicator leaving holes 16 and traveling along the catheter, along with by sensing the exit pulse of the bolus which would travel along a length of the catheter); and calculating the blood flow rate (see col. 5 line 60 – col. 6 line 1) as a function of the sensed indicator (at least by its temperature

gradient and time characteristics). Smith ‘103 further discloses that a volume less than a total volume of the indicator passed through the indicator lumen is injected into the blood vessel (see col. 4 lines 19-34). However, it is unclear whether Smith '103 calculates the blood flow rate as a function of less than a total volume the indicator passed through the terminal port. Smith ‘103 does however note that the flow parameter is calculated similarly to the method found in WO 97/27802, of which Smith '514 is a continuation (col. 5 lines 60-65).

Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have similarly used the total volume of injected indicator to determine the blood flow rate, as Smith ‘103 explicitly states that this method “is suitable for the determination of the so called Coronary Fractional Reserve (CRF)” (col. 5 lines 60-63), and Smith ‘103 uses the blood flow rate to calculate CFR.

Because Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate, and Smith '103 discloses that the total volume of injected indicator is less than the total volume of the indicator passed through the indicator lumen, this combination renders obvious the claimed invention.

7. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ‘103 in view of Smith ‘514 as applied to claim 14 above, and further in view of US Pat. No. 5,221,256 to Mahurkar ("Mahurkar").

In reference to Claims 16 and 18

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses passing the guide wire through the indicator lumen to increase a flow of the indicator through the injection port (as its presence would increase flow through these compared with a situation in which it was not there) but does not explicitly teach a reduced cross sectional area of the indicator lumen. Mahurkar teaches (see Fig. 4) a catheter with a fluid injection lumen with multiple ports (21, 22). The injection lumen tapers and has a reduced cross-sectional area at its tip. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Smith '103 in view of Smith '514 by making the catheter with a similar tip and lumen configuration so that the distal tip would be more flexible and atraumatic as implicitly taught by Mahurkar.

Response to Arguments

8. Applicant's arguments, see pgs. 7-9, filed 5/16/2011, with respect to claims 14, 30, and 31 have been fully considered and are persuasive. The claim objections, rejections under 35 U.S.C. 112, first and second paragraphs, and double patenting rejections of 1/9/2011 have been withdrawn.

9. Applicant's arguments with respect to claim 29 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's remaining arguments filed 5/16/2011 have been fully considered but they are not persuasive. In response to Applicant's arguments that because Smith '103

discloses that “the total volume of indicator that has passed through the Smith ‘103 catheter is total volume of injected indicator” Smith ‘103 in view of Smith ‘514, the Examiner respectfully disagrees. Claims 14 and 30 currently requires "passing an indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port located along the longitudinal axis intermediate the terminal port and a proximal end of the catheter body . . . calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen". The claim does not define “a total volume of the indicator passed through the indicator lumen” to be equivalent to, for example, an amount of indicator that exits the terminal port and the injection port. Therefore, the limitation has been broadly interpreted to include all indicator that has passed through the indicator lumen, including indicator that has not passed completely through the indicator lumen and exited one of the ports. This interpretation is analogous to saying that guidewire 2 of Smith ‘103 has passed through the indicator lumen in Fig. 3, while a portion of the guidewire remains within the lumen. Therefore, the Examiner maintains that Smith '103 in view of Smith '514 discloses the claimed feature.

11. In response to Applicant’s arguments (pg. 14) regarding claim 19 “[t]hat Smith ‘103 uses the total volume cannot sustain a rejection of compensating”, the Examiner respectfully disagrees. The claim does not define in any way *how* the calculating compensates for a volume of the indicator passing through the terminal port. The method of Smith ‘103 in view of Smith ‘514 compensates for a volume of indicator passing through the terminal port by acknowledging that this is not the only amount of

indicator exiting the device, and compensates by using the total volume, rather than merely the amount exiting the terminal port.

12. In response to Applicant's arguments regarding claim 20 (pgs. 15-16), the Examiner respectfully disagrees. Applicant cites *Diamond v. Diehr* in an attempt to support Applicant's position that "the use of an equation" is not obvious. This is unpersuasive for several reasons. The Examiner's position was not that the mere use of an equation in a claim is *per se* obvious, but merely that the particular language of the claim is broad enough that the cited art discloses it. Claim 20 in no way positively requires the use of the equation found in the claim, but merely that "the calculated blood flow rate is described by a relationship . . . the calculated blood flow rate being a value provided by an appropriate selection of k, T_b, T_i, V, S and a." In the context of the claims, claim 20 merely requires that the value provided by the "calculating" in claim 14 would abstractly be a number that is described by an appropriate selection of values. Referring to the Diehr patent (US Pat. No. 4,344,142), the claim language (see e.g. claim 1 of Diehr) intimately links the equation to values that are found in a computer database and explicitly used by a computer in the method. Applicant's claim 20 does not tie the variables to the rest of the method in a meaningful way. For example, the variables do not explicitly refer to values defined in claim 14, or to values tied to structures or steps found in claim 14, but merely to values that are unbounded and undefined with respect to the meaningful aspects of the claim. This is the basis for the Examiner's assertion that "any numerical value could be generated using the claimed relationship of claim 20 by selecting the appropriate combination of values for the

parameters". Whatever blood flow rate was calculated in claim 14 would be described by an appropriate selection of the variables (i.e. a selection of variables that would lead to the same numerical value as that provided by the calculation in claim 14) and this would be consistent with the breadth of the claim.

13. In response to Applicant's arguments regarding claim 28, the Examiner respectfully disagrees. It is unclear exactly what Applicant believes is the distinction in the amended claim, but the Examiner maintains that Smith '103 discloses "sensing the indicator along the longitudinal axis intermediate the terminal port and the injection port" because the sensor 4 has an extension orthogonal to the longitudinal axis that would be intermediate the terminal port and the injection port and lies along the longitudinal axis. This is clearly consistent with Applicant's invention in which the sensor is located along the longitudinal axis in the sense that it lies near it; the longitudinal axis of the catheter body does not pass through sensor 36 of the Applicant's invention.

14. In response to Applicant's arguments regarding claim 31, the Examiner maintains that claim 31 is obvious for the reasons details above regarding claim 14 and for the reasons found in the detailed description of the rejection of claim 31 above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 10:00 am - 6:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 6/3/11

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736